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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,465	02/07/2005	Matthew H T Bui	306J-000220US	4663

20350 7590 09/04/2008

TOWNSEND AND TOWNSEND AND CREW, LLP
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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,465	BUI ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-23 and 26* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 7-23 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 1, 4, 5, 7-24 and 26 are pending.

Claim 4, drawn to non-elected inventions are withdrawn from examination.

Claims 1 and 14 have been amended.

Claims 2, 3, 6, 24 and 25 have been cancelled.

Claim 26 has been added.

Claims 1, 5, 7-23 and 26 to the extent the CAIX is a polypeptide are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 14-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' amendment to claim 14.

4. The rejection of claims 1-3, 6-14 and 16-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1, 5-14 and 16-23 under 35 U.S.C. 102(b) as being anticipated by Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) is withdrawn because Zisman does not disclose immunohistochemical analysis. Claims 2, 3 and 6 have been cancelled.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1, 5 and 7-23 under 35 U.S.C. 103(a) as being unpatentable over Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005), and further in view of U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005) is withdrawn in light of Applicants' amendments. Claims 2, 3 and 6 have been cancelled.

Maintained and New Rejections

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 1, 5 and 7-13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Claims 2, 3 and 6 have been cancelled.

Applicants arguments directed toward the instant rejection are improperly set forth under 35 U.S.C. 112, second paragraph statute, see page 11 of the Remarks. However, arguments directed toward the instant rejection were considered and found unpersuasive. Applicants aver with the amendments to the base claims, the instant rejection should be withdrawn. Applicants argue that have done more than the law requires and they were in possession of the claimed subject matter, see page 11 and 12. As noted earlier in this paragraph, Applicants' arguments and amendments have been carefully considered, but found unpersuasive.

Applicants have amended base claim 14 to reflect CAIX corresponds to SEQ ID NO: 2, but that amendment has not been presented in base claim 1. The recitations, "human" and "protein" do not help Applicants' preclude the instant rejection. The recitation, "human carbonic anhydrase IX (CAIX) protein" is not a limiting phrase. This terminology still reads on a CAIX molecule which may be a variant or mutant of SEQ ID

NO: 2. Furthermore, the claims do not set forth human CAIX corresponds to SEQ ID NO: 2. For the reasons of record and set forth above the rejection is maintained.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 1, 5, 7-11, 14-16, 18-23 and newly added claim 26 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005) is maintained and newly made. Claims 2, 3 and 6 have been cancelled.

Applicants assert the patent teaches away from the claimed invention and cites a reference, Ivanov separate and distinct from the instant rejection, see Remarks submitted June 12, 2008, bridging paragraph of pages 14 and 15. These arguments and points of view listed herein and in the Remarks have been carefully considered, but found unpersuasive.

The patent discloses a method of quantitating MN antigen also art known as CAIX located in a patient sample implementing an immunoassay, such as immunohistochemical assays, ELISAS or fluorometric assays, see sequence alignment at conclusion of this rejection; column 5, lines 49-column 6, line 3; column 6, lines 47-

54; column 36, line 44-column 39, line 35; and Example 13 starting in column 55. Applicants' claims set forth one active step listed in claim 1 (a), quantifying by immunohistochemical staining or immunoassay expressed human CAIX protein and hence reads on a method of aiding in RCC prognosis and correlating the expression data with a probability of RCC prognosis, wherein the quantified CAIX expression data comprises the claimed quantification percentages and correlates with positive responses. For the reasons of record and further established herein the rejection is maintained and made.

```
RESULT 1
US-08-481-658B-2
; Sequence 2, Application US/08481658B
; Patent No. 5955075
;  GENERAL INFORMATION:
;    APPLICANT:  Zavada, Jan
;    APPLICANT:  Pastorekova, Silvia
;    APPLICANT:  Pastorek, Jaromir
;    TITLE OF INVENTION:  MN Gene and Protein
;    NUMBER OF SEQUENCES:  86
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Leona L. Lauder
;      STREET:  6 Mariposa Court
;      CITY:  Tiburon
;      STATE:  California
;      COUNTRY:  USA
;      ZIP:  94920
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Floppy disk
;      COMPUTER:  IBM PC compatible
;      OPERATING SYSTEM:  PC-DOS/MS-DOS
;      SOFTWARE:  PatentIn Release #1.0, Version #1.30 (EPO)
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/481,658B
;      FILING DATE:  07-JUN-1995
;      CLASSIFICATION:  424
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:  US 08/260,190
;      FILING DATE:  15-JUN-1994
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Lauder, Leona L.
;      REGISTRATION NUMBER:  30,863
;      REFERENCE/DOCKET NUMBER:  D-0021.3E
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  415-435-2034
;      TELEFAX:  415-435-0727
;  INFORMATION FOR SEQ ID NO:  2:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  459 amino acids
;      TYPE:  amino acid
;      STRANDEDNESS:
;      TOPOLOGY:  linear
;    MOLECULE TYPE:  protein
```

```
;      DESCRIPTION:  First 37 amino acids represent
;      DESCRIPTION:  signal peptide, and remaining amino acids
;      DESCRIPTION:  represent mature protein
US-08-481-658B-2

  Query Match             100.0%;  Score 2424;  DB 1;  Length 459;
  Best Local Similarity   100.0%;  Pred. No. 2.7e-196;
  Matches  459;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MAPLCPSPWLPLLIPAPAPGLTVQLLLSLLLLMPVHPQRLPRMQEDSPLGGGSSGEDDPL 60
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MAPLCPSPWLPLLIPAPAPGLTVQLLLSLLLLMPVHPQRLPRMQEDSPLGGGSSGEDDPL 60

Qy         61 GEEDLPSEEDSPREEDPPGEEDLPGEEDLPGEEDLPEVKPKSEEEGSLKLEDLPTVEAPG 120
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GEEDLPSEEDSPREEDPPGEEDLPGEEDLPGEEDLPEVKPKSEEEGSLKLEDLPTVEAPG 120

Qy        121 DPQEPQNNAHRDKEGDDQSHWRYGGDPPWPRVSPACAGRFQSPVDIRPQLAAFCPALRPL 180
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 DPQEPQNNAHRDKEGDDQSHWRYGGDPPWPRVSPACAGRFQSPVDIRPQLAAFCPALRPL 180

Qy        181 ELLGFQLPPLPELRLRNNGHSVQLTLPPGLEMALGPGREYRALQLHLHWGAAGRPGSEHT 240
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 ELLGFQLPPLPELRLRNNGHSVQLTLPPGLEMALGPGREYRALQLHLHWGAAGRPGSEHT 240

Qy        241 VEGHRFPAEIHVVHLSTAFARVDEALGRPGGLAVLAAFLEEGPEENSAYEQLLSRLEEIA 300
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 VEGHRFPAEIHVVHLSTAFARVDEALGRPGGLAVLAAFLEEGPEENSAYEQLLSRLEEIA 300

Qy        301 EEGSETQVPGLDISALLPSDFSRYFQYEGSLTTPPCAQGVIWTVFNQTVMLSAKQLHTLS 360
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 EEGSETQVPGLDISALLPSDFSRYFQYEGSLTTPPCAQGVIWTVFNQTVMLSAKQLHTLS 360

Qy        361 DTLWGPGDSRLQLNFRATQPLNGRVIEASFPAGVDSSPRAAEPVQLNSCLAAGDILALVF 420
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 DTLWGPGDSRLQLNFRATQPLNGRVIEASFPAGVDSSPRAAEPVQLNSCLAAGDILALVF 420

Qy        421 GLLFAVTSVAFLVQMRRQHRRGTKGGVSYRPAEVAETGA 459
              |||||||||||||||||||||||||||||||||||||||
Db        421 GLLFAVTSVAFLVQMRRQHRRGTKGGVSYRPAEVAETGA 459
```

11. Claims 1, 5, 7-11, 14-16, 18-23 and newly added claim 26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/34650 (published December 21, 1995). The WO document discloses a method of quantitating MN antigen also art known as CAIX located in a patient sample implementing an immunoassay, such as immunohistochemical assays, ELISAS or fluorometric assays, see sequence alignment at conclusion of this rejection; abstract; page 10, line 22-page 11, line 4; page 52, line 26-page 55, line 13. Applicants' claims set forth one active step listed in claim 1 (a), quantifying by immunohistochemical staining or immunoassay expressed human CAIX protein and hence reads on a method of aiding in RCC prognosis and correlating the expression data with a probability of RCC prognosis, wherein the quantified CAIX expression data comprises the claimed quantification percentages and correlates with positive responses. For the reasons of record and further established herein the rejection is maintained and made.

RESULT 1

```
AAR88058
ID   AAR88058 standard; protein; 459 AA.
XX
AC   AAR88058;
XX
DT   15-JUN-2007  (revised)
DT   25-MAR-2003  (revised)
DT   25-JUL-1996  (first entry)
XX
DE   Protein encdoed by MuTu putative oncogene MN.
XX
KW   MuTu; endogenous; cellular component; MN; HeLa cell; diagnosis;
KW   lymphocytic choriomeningitis virus; LCMV; putative oncogene; treatment;
KW   neoplastic; pre-neoplastic; disease; antisense therapy; antibody;
KW   vaccine; vertebrate; immunisation; carbonic anhydrase; BOND_PC;
KW   carbonic anhydrase IX; carbonic anhydrase IX precursor;
KW   carbonic dehydratase; RCC-associated protein G250;
KW   carbonic anhydrase IX precursor [Homo sapiens]; CA9; MN; CAIX;
KW   Carbonic anhydrase IX [Homo sapiens]; p54/58N; p54/58N [Homo sapiens];
KW   renal cell carcinoma associated antigen G250; carbonic anhydrase;
KW   renal cell carcinoma associated antigen G250 [Homo sapiens];
KW   carbonic anhydrase IX [synthetic construct]; GO2009; GO4089; GO5634;
KW   GO6730; GO8270; GO16020; GO16021; GO16829; GO46872; GO46903.
XX
OS   Homo sapiens.
XX
```

```
FH   Key             Location/Qualifiers
FT   Peptide         1. .37
FT                   /label= sig_peptide
FT   Peptide         36. .51
FT                   /note= "anti-MN antibody epitope"
FT   Region          38. .135
FT                   /note= "region homologous to collagen alpha 1 chain"
FT   Peptide         55. .60
FT                   /note= "anti-MN antibody epitope"
FT   Peptide         62. .67
FT                   /note= "anti-MN antibody epitope"
FT   Peptide         68. .91
FT                   /note= "anti-MN antibody epitope"
FT   Peptide         127. .147
FT                   /note= "anti-MN antibody epitope"
FT   Domain          136. .391
FT                   /note= "carbonic anhydrase domain"
FT   Peptide         279. .291
FT                   /note= "anti-MN antibody epitope"
FT   Region          414. .433
FT                   /note= "intracellular transmembrane region"
FT   Region          434. .459
FT                   /note= "intracellular C-terminus"
FT   Peptide         435. .450
FT                   /note= "anti-MN antibody epitope"
XX
PN   WO9534650-A2.
XX
PA   (CIBA ) CIBA CORNING DIAGNOSTICS CORP.
PA   (VIRO-) INST VIROLOGY.
XX
PI   Zavada J,  Pastorekova S,  Pastorek J;
XX
DR   WPI; 1996-049679/05.
DR   N-PSDB; AAT09186.
DR   PC:NCBI; gi9955948.
DR   PC:SWISSPROT; Q16790.
XX
PT   MN gene, protein and nucleic acid fragments - used as primers and probes
PT   in the detection of MN antigens and antibodies, and in the treatment of
PT   (pre)neoplastic disease.
XX
PS   Claim 12; Fig 1; 102pp; English.
XX
CC   The present sequence is encoded by the full length MuTu endogenous
CC   cellular component, MN, cDNA clone, which was isolated from lymphocytic
CC   choriomeningitis virus (LCMV) infected HeLa cells. Persistent LCMV, the
CC   exogenous MuTu transmissible agent (MX), infection increases the
CC   expression level of the MN gene. MN is a putative oncogene, and can
CC   therefore be used in the development of prods. for the diagnosis and
CC   treatment of neoplastic (NP), or pre-NP diseases. NP diseases can be
CC   treated using DNA antisense to MN transcribed mRNA, anti-MN protein
CC   antibodies can be used for the diagnosis NP or pre-NP diseases and a
CC   vaccine contg. immunogenic amounts of the MN protein can be used to
CC   immunise a vertebrate against a NP disease associated with MN antigen
CC   expression. (Updated on 25-MAR-2003 to correct PR field.)
CC
CC   Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC   information from BOND.
XX
SQ   Sequence 459 AA;

  Query Match             100.0%;  Score 2424;  DB 2;  Length 459;
  Best Local Similarity   100.0%;  Pred. No. 3.9e-182;
  Matches  459;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MAPLCPSPWLPLLIPAPAPGLTVQLLLSLLLLMPVHPQRLPRMQEDSPLGGGSSGEDDPL 60
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                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MAPLCPSPWLPLLIPAPAPGLTVQLLLSLLLLMPVHPQRLPRMQEDSPLGGGSSGEDDPL 60

Qy         61 GEEDLPSEEDSPREEDPPGEEDLPGEEDLPGEEDLPEVKPKSEEEGSLKLEDLPTVEAPG 120
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GEEDLPSEEDSPREEDPPGEEDLPGEEDLPGEEDLPEVKPKSEEEGSLKLEDLPTVEAPG 120

Qy        121 DPQEPQNNAHRDKEGDDQSHWRYGGDPPWPRVSPACAGRFQSPVDIRPQLAAFCPALRPL 180
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 DPQEPQNNAHRDKEGDDQSHWRYGGDPPWPRVSPACAGRFQSPVDIRPQLAAFCPALRPL 180

Qy        181 ELLGFQLPPLPELRLRNNGHSVQLTLPPGLEMALGPGREYRALQLHLHWGAAGRPGSEHT 240
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 ELLGFQLPPLPELRLRNNGHSVQLTLPPGLEMALGPGREYRALQLHLHWGAAGRPGSEHT 240

Qy        241 VEGHRFPAEIHVVHLSTAFARVDEALGRPGGLAVLAAFLEEGPEENSAYEQLLSRLEEIA 300
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 VEGHRFPAEIHVVHLSTAFARVDEALGRPGGLAVLAAFLEEGPEENSAYEQLLSRLEEIA 300

Qy        301 EEGSETQVPGLDISALLPSDFSRYFQYEGSLTTPPCAQGVIWTVFNQTVMLSAKQLHTLS 360
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 EEGSETQVPGLDISALLPSDFSRYFQYEGSLTTPPCAQGVIWTVFNQTVMLSAKQLHTLS 360

Qy        361 DTLWGPGDSRLQLNFRATQPLNGRVIEASFPAGVDSSPRAAEPVQLNSCLAAGDILALVF 420
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 DTLWGPGDSRLQLNFRATQPLNGRVIEASFPAGVDSSPRAAEPVQLNSCLAAGDILALVF 420

Qy        421 GLLFAVTSVAFLVQMRRQHRRGTKGGVSYRPAEVAETGA 459
                 |||||||||||||||||||||||||||||||||||||
Db        421 GLLFAVTSVAFLVQMRRQHRRGTKGGVSYRPAEVAETGA 459
```

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The rejection of claims 1, 5, 7-23 and newly added claim 26 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) is maintained and made. Claims 2, 3 and 6 have been cancelled.

Applicants did not traverse this rejection, see entire Remarks submitted June 12, 2008. Nonetheless, the rejection is maintained for the reasons of record and further established in the 102(b) rejection.

14. Claims 1, 5, 7-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005). The teachings of the document have been presented above. The document does not teach the quantified CAIX expression data in a computer-readable form, wherein there is a programmable computer with a database and an algorithm.

However, Zisman teaches a method of quantifying expressed CAIX in samples from patients with RCC and the data and characteristics of this evaluated population using Stata statistical software, see page 1650, 2nd column, last paragraph of Survival...section and Results. The disclosed system allows one of ordinary skill in the art to prognosticate and determine survival differences imposed by different histologic types of RCC, see page 1657. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the computer based program of Zisman. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both documents that CAIX is a diagnostic marker for tumorigenicity and is prognostic for neoplastic/pre-neoplastic disease, as well as the system of Zisman stratifies and

analyzes data for discriminating patient prognosis, see patent, column 1, lines 15-25; and column 2, lines 1-9; and the entire Zisman article.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
02 September 2008
/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643